APR - 6 2001

K 002889

510(k) Summary
for
Neotonus PNS Magnetic Stimulator System

1. SPONSOR

Neotonus, Inc.
835-B Franklin Court SE
Marietta, GA 30067

Contact Person: Tony J. Morris, President/CEO
Telephone: 770-428-7356

Date Prepared: September 14, 2000

2. DEVICE NAME

Proprietary Name: PNS Magnetic Stimulator
Common/Usual Name: Magnetic Stimulator
Classification Name: Evoked Response Electrical Stimulator

3. PREDICATE DEVICES

Cadwell High Speed Magnetic Stimulator (K905059)
Magstim Rapid (K992911)

4. INTENDED USE

The Neotonus PNS Magnetic Stimulator System is intended for stimulation of peripheral nerves.

5. DEVICE DESCRIPTION

The PNS Magnetic Stimulator System consists of a Control Unit, used to generate and control the stimulus signal, and a Stimulation Head, used to deliver the stimulus signal to the target nerve(s). The Control Unit is connected to the Stimulation Head via an insulated electrical cable.

The stimulation parameters (i.e., power level, frequency, on-time, and off-time) are fed into the Power unit, which provides the signal used to charge the magnetic core. The DC voltage input to the Power Unit charges the capacitor circuitry according to the intensity set by the power level control. The capacitor circuitry is then discharged through the inductive magnetic core according to the periodic sequence as set by the operator. The periodic charging and discharging of the capacitor through the core creates the magnetic field transient, which induces the electrical field within the tissue.

During stimulation, the Stimulation Head is held against the patient's skin over the target nerve(s) by the clinician. The stimulation head can be strapped in place after proper positioning by the clinician.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The PNS Magnetic Stimulator System is substantially equivalent to several legally marketed magnetic stimulator devices including the Cadwell High Speed Magnetic Stimulator (K905059) and Magstim Rapid (K992911).

The PNS Magnetic Stimulator System is identical to the predicate devices in intended use in that they are all magnetic stimulators intended to provide totally non-invasive peripheral nerve stimulation for clinical research and diagnosis of nerve conditions.

The technological characteristics of the PNS Magnetic Stimulator System are similar to those of the predicate devices. All devices induce an action potential in the target nerve(s) using magnetic stimulation. All devices are capable of both single pulse and rapid rate output. Finally, all of the devices include a control unit, for user control of the various stimulation parameters, and a stimulation applicator containing the coil component.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Neotonus, Inc.
c/o Ms. Sheila Hemeon-Heyer, J.D., R.A.C.
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K002889
Trade Name: Neotonus PNS Magnetic Stimulator System
Regulatory Class: II
Product Code: KOI, GWF
Dated: January 10, 2001
Received: January 11, 2001

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002889

Device Name:

Neotonus PNS Magnetic Stimulator System

Indications For Use:

The Neotonus PNS Magnetic Stimulator System is intended for stimulation of peripheral nerves.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002889

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)